



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1434]

Draft Guidance for Industry on Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules." This guidance discusses FDA recommendations for the size, shape, and other physical attributes of generic tablets intended to be swallowed intact. FDA is concerned that these characteristics of generic drugs are too varied compared to the originator drug and could affect patient outcomes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Debra Catterson, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 240-402-3861; or Vilayat Sayeed, Center for Drug Evaluation and Research (HFD-630), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8486.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules.” FDA is concerned that the differences in size, shape, and other physical characteristics between the generic and the originator could adversely affect patient outcomes. For example, studies show that tablet size can affect ease of swallowing, and generic tablets that are significantly larger than their corresponding reference drug product may be more difficult to swallow, leading to potential adverse events as well as noncompliance with treatment regimens. FDA is recommending generic manufacturers consider the size, shape, and other physical characteristics of the originator drug when developing a generic version.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on tablet size, shape, and other physical attributes of generic solid oral dosage

forms. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collection of information requested in the draft guidance is covered under FDA regulations at 21 CFR 314 and approved under OMB control number 0910-0001. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-29395 Filed 12/09/2013 at 8:45 am; Publication Date: 12/10/2013]